THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MELANIE ATKINSON **Plaintiff,** **v.** **LUITPOLD PHARMACEUTICALS, INC., AMERICAN REGENT, INC., DAIICHI SANKYO, INC., DAIICHI SANKYO CO., LTD., AND VIFOR PHARMACEUTICALS MANAGEMENT, LTD.,** **Defendants.**	**CIVIL ACTION** **NO. 19-277**

OPINION

Plaintiff Melanie Atkinson brings negligence, fraud, strict liability, breach of warranty, and breach of consumer protection law claims following purported adverse effects she suffered after receiving injections of Injectafer, a medication prescribed to treat iron deficiency anemia. Defendants American Regent, Inc., formerly known as Luitpold Pharmaceuticals, Inc.,[1] Daiichi Sankyo, Inc., and Daiichi Sankyo US Holdings, Inc. (collectively, "Defendants") move to dismiss most of the Complaint pursuant to Federal Rule of Civil Procedure 12(b)(6).

I. FACTS[2]

Injectafer is an iron replacement injection medication brought to market in the United States by Defendants for the treatment of iron deficiency anemia ("IDA") in adult patients who have intolerance to oral iron. The injection is to be administered intravenously in two doses separated by at least seven days.

[1] Effective January 1, 2019, Luitpold Pharmaceuticals, Inc. merged with American Regent, Inc..

[2] These facts are drawn from the Complaint and, for the purposes of the motion to dismiss, will be taken as true. *See Kost v. Kozakiewicz*, 1 F.3d 176, 183 (3d Cir. 1993).

Injectafer is one of several products available for intravenous iron but is the only such product available in the United States formulated with the unique ferric carboxymaltose ("FCM") compound. FCM can cause a condition called severe hypophosphatemia ("Severe HPP"). Hypophosphatemia is an abnormally low level of phosphate in a person's blood, and the condition can be mild, moderate, severe, or persistent. Severe HPP has dangerous effects including muscle weakening, fatigue, severe nausea, and possible medical complications including cardiac arrest, respiratory failure, arrhythmias, and rhabdomyolysis (muscle breakdown).

Prior to its approval in the United States, FCM was available on the European and other markets under the brand name Ferinject—designed, manufactured, promoted, and sold by Defendant Vifor Pharmaceuticals. (Vifor licensed and continues to license FCM to all other Defendants.) During FCM's presence on the European and United States markets, dozens of case reports and pieces of medical literature emerged that revealed the link between FCM and Severe HPP. The studies, of which Defendants were on notice, revealed an increasing number of case reports of intravenous-iron patients developing Severe HPP. In one study, all 18 cases of severe and life-threatening HPP developed after administration of FCM. In another study, of the 78 patients taking FCM, 51% developed HPP, including 13% with Severe HPP. Defendants also had knowledge of the link between Injectafer and Severe HPP from their own clinical studies.

When Luitpold Pharmaceuticals, Inc. ("Luitpold") first submitted a New Drug Application for Injectafer to the Food and Drug Administration ("FDA") in 2006, it received a non-approvable letter in response due to the FDA's clinical safety concerns. Luitpold applied again in September 2007 and received another non-approvable letter, which cited "clinically important hypophosphatemia" as a concern. Injectafer eventually received FDA approval, and in

2013 Defendants brought Injectafer to the United States market.

Since then, Injectafer's label has at all times omitted any reference to "Severe HPP" or "clinically important hypophosphatemia."[3] HPP is not listed in the warning sections or in any kind of "black box" warning, but instead is listed as an "adverse reaction" occurring in less than two percent of patients. From July 2013 until January 2018, the Patient Information leaflet referred to "asymptomatic reductions in blood phosphorus." In January 2018, Defendants removed the term "asymptomatic" and simply listed "low levels of phosphorous in your blood" in the leaflet. The "Adverse Reactions in Clinical Trials" section of the labeling refers to "transient decreases in laboratory blood phosphorous levels (< 2 mg/dl)." The labeling makes no reference to clinical conditions associated with Severe HPP, including cardiac arrest, respiratory failure, arrhythmias, and rhabdomyolysis (muscle breakdown). The labeling also does not reference FCM's known effect on the FGF23 hormone, which is associated with a decrease in blood phosphorous and can induce HPP.

Plaintiff, a Texas resident, was prescribed Injectafer for the treatment of her IDA at the Medical Clinic of Houston in Houston, Texas. She received her first Injectafer injection at the clinic on or around October 20, 2016. After that injection, Plaintiff's blood phosphate levels dropped to 1.0 mg/dl, as measured on November 21. She was subsequently diagnosed with HPP, was hospitalized multiple times, and suffered from severe nausea, severe weakness and pain, and severe and constant fatigue. She took a leave of absence from work and was only able to return

[3] Defendants have attached to their motion to dismiss a copy of the Injectafer Prescribing Information from July 2013, which they allege was in effect at the time of Plaintiff's prescription. "[A] court may consider any undisputedly authentic document that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff's claims are based on the document" without converting a motion to dismiss into one for summary judgment. *Pension Benefit Guar. Corp. v. White Consol. Indus.*, 998 F.2d 1192, 1196 (3d Cir. 1993). Neither party disputes the authenticity of the Prescribing Information. Given that Plaintiff's Complaint challenges Injectafer's labeling, warning, and patient information, the Prescribing Information may be considered in ruling on Defendants' motion to dismiss.

after several months on limited duties. Plaintiff filed this suit, alleging that she suffered and likely will continue to suffer severe and permanent injuries and damages as a result of taking Injectafer. Defendants have now moved to dismiss all claims, in whole or in part.

II. LEGAL STANDARDS

When evaluating a complaint on a motion to dismiss factual allegations are scrutinized under Rules 8(a) and 12(b)(6) to determine if the allegations and inferences proposed from those allegations are plausible. *See Ashcroft v. Iqbal*, 556 U.S. 662, 683 (2009). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *See id.* at 678 (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

"In light of *Twombly*, 'it is no longer sufficient to allege mere elements of a cause of action; instead a complaint must allege facts suggestive of [the proscribed] conduct.'" *Great W. Mining & Mineral Co. v. Fox Rothschild LLP*, 615 F.3d 159, 177 (3d Cir. 2010) (quoting *Phillips v. Cty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008)). "[R]ote recitals of the elements of a cause of action, legal conclusions, and mere conclusory statements" are disregarded. *James v. City of Wilkes-Barre*, 700 F.3d 675, 679 (3d Cir. 2012). The relevant question is not whether the claimant "will ultimately prevail . . . but whether [the] complaint [is] sufficient to cross the federal court's threshold." *Skinner v. Switzer*, 562 U.S. 521, 531 (2011).

III. ANALYSIS[4]

Plaintiff's Complaint includes 11 numbered claims. Each claim contains some or all of

[4] A federal court sitting in diversity must apply state substantive law and federal procedural law. *See Erie R.R. v. Tompkins*, 304 U.S. 64, 78 (1938). This Court previously ruled that the substantive law of the state in which the claim arose, Texas, governs this action. *See Atkinson v. Luitpold Pharms., Inc.*, 414 F. Supp.3d 742, 747 (E.D. Pa. 2019). The parties do not dispute that Texas substantive law applies except with respect to punitive damages: Plaintiff believes Texas law applies, while Defendants believe Pennsylvania law applies.

the following theories: that Defendants designed, developed, manufactured, marketed, promoted, monitored, labeled, sold, and distributed Injectafer while knowing or reasonably suspecting that the drug was dangerous. Count II is a negligent failure-to-warn claim. Count III is a negligent design defect claim. Count IV is a negligent misrepresentation claim. Count I is a catch-all negligence claim, which uses all the aforementioned theories to allege Defendants had a duty of care to patients and physicians which they breached in developing and distributing a drug they knew to be unreasonably dangerous without adequate warnings. Count V is a fraud claim, alleging Defendants falsely represented Injectafer to patients and doctors by concealing its known risks to induce more Injectafer prescriptions. Counts VI and VII are strict liability claims for failure to warn and for design defect, respectively. Count VIII is a breach of express warranty claim, alleging Defendants represented through language in their labeling, advertising, and marketing materials that Injectafer was safe for patient use. Count IX is a breach of implied warranty claim, alleging that Defendants implied through their labeling, advertising, and marketing that Injectafer was safe. Count X is a breach of state consumer protection laws claim, alleging Defendants deceived patients by claiming Injectafer was safe and advertising the drug in a way that created misunderstandings about its risks. Count XI is a gross negligence claim. Additionally, Plaintiff seeks punitive damages.

In her brief in opposition to the motion to dismiss, Plaintiff states that she is no longer pursuing Count III (negligent design defect), Count IV (negligent misrepresentation), Count VIII (breach of express warranty), Count IX (breach of implied warranty), and Count X (breach of consumer protection laws). Those claims will accordingly be dismissed with prejudice.

A. Preemption

Defendants argue that any of Plaintiff's claims that are premised on a failure to warn are

preempted by federal law in that they boil down to the theory that Injectafer should have been labeled and designed differently despite FDA approval of the existing label and design.[5]

The Supremacy Clause provides that federal law "shall be the supreme Law of the Land." U.S. Const., Art. VI, cl. 2. State law that conflicts with federal law is therefore "without effect." *Mutual Pharm. Co. v. Bartlett*, 570 U.S. 472, 475 (2013). There are three categories of preemption: (1) express preemption, (2) field preemption, and (3) conflict or impossibility preemption, *see Orson, Inc. v. Miramax Film Corp.*, 189 F.3d 377, 381 (3d Cir. 1999), but only the last one is at issue here.

Conflict preemption is "for a judge to decide, not a jury." *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1672 (2019); *see also id.* at 1678 (noting that "the complexity" of the legal discussion "helps to illustrate why" conflict preemption should be determined by a judge). Indeed, when conflict preemption presents a purely legal issue, the Court may decide it on a Rule 12 motion. *See, e.g.*, *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 623-24 (2011); *Riegel v. Medtronic*, 552 U.S. 312 (2008); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). In deciding whether conflict preemption requires the dismissal of a claim, the judge must "simply ask . . . whether the relevant federal and state laws 'irreconcilably conflict.'" *Merck*, 139 S. Ct. at 1679 (quoting *Rice v. Norman Williams Co.*, 458 U.S. 654, 659 (1982)).

In a motion to dismiss a related case, *Crockett,* Defendants made the same preemption argument.[6] They argued that the FDA approval process was "onerous" and "lengthy" and referred to two non-approvable letters from the FDA which cited concerns about "clinically

[5] As in *Crockett v. Luitpold Pharmaceuticals, Inc.,* 2020 WL 433367 (E.D. Pa. Jan. 28, 2020), Defendants' preemption challenge here is limited to Plaintiff's pre-approval failure-to-warn and defective design claims. Plaintiff concedes that she is not making a post-approval design defect claim, and Defendants are not seeking dismissal of Plaintiff's claim that Defendants negligently failed to change the Injectafer label post-approval.
[6] Plaintiff's case is one of nineteen such Injectafer cases filed thus far, all of which are before this Judge.

important hypophosphatemia[,]" but they did not argue or point to any evidence that they proposed a stronger warning to the FDA or that the FDA would have rejected a different warning label. *Crockett,* 2020 WL 433367, at *8. Accordingly, the Court held that Defendants had not met the standard for impossibility preemption to show that they "fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve changing the drug's label to include that warning." *Id.* (quoting *Merck*, 139 S. Ct. at 1678). Because Defendants had not met their burden, the Court found that a ruling on preemption with respect to Plaintiff's failure-to-warn and defective design claims would be premature. *Id.* Defendants here advance the same preemption arguments, based on the same federal law and a complaint that is identical to the one in *Crockett* in all legally material ways. Because the same analysis applies here, the pre-approval design-defect claim is not preempted. However, this case presents an additional and unique preemption question because (as the parties agree) Texas law is the substantive law of the case and Section 82.007 of the Texas Civil Practice & Remedies Code implicates Plaintiff's failure-to-warn claims. *See* Tex. Civ. Prac. & Rem. Code § 82.007(a)(1). More specifically, Defendants argue that each of Plaintiff's claims which are premised on a failure-to-warn theory are barred by Section 82.007, pursuant to which "a drug manufacturer enjoys a rebuttable presumption that it is not liable for failure to warn if the [Federal Drug Administration ("FDA")] has approved 'the warnings of information' accompanying the product alleged to have harmed the Plaintiff." *Lofton v. McNeil Consumer & Specialty Pharm.*, 672 F.3d 372, 374 (5th Cir. 2012).

i. The Texas Statute

Section 82.007, which was adopted as a tort reform measure to restrict certain common

law claims concerning FDA-approved drugs, gives drug manufacturers a rebuttable presumption in products liability cases that they are not liable for failure-to-warn claims if the FDA has approved the product's warning label. *See id.* at 374, 376. Section 82.007(a)(1) creates a statutory presumption that drug manufacturers are not liable for failure-to-warn claims if the FDA has approved the drug's label. Specifically:

> In a products liability action alleging that an injury was caused by a failure to provide adequate warnings of information with regard to a pharmaceutical product, there is a rebuttable presumption that the defendant or defendants . . . are not liable with respect to the allegations involving failure to provide adequate warnings or information. . . .

Id. § 82.007(a)(1).

Included in the statute are five limited ways to rebut this presumption: (1) if the defendant withheld from or misrepresented material information to the FDA; (2) if the drug was sold after an order from the FDA to remove the product from the market; (3) if the product was used as recommended or advertised, and the injury was causally related to the promoted use; (4) if the defendant prescribed the drug for an indication not approved by the FDA; or (5) if the defendant bribed a public official before or after approval, causing the warnings to be inadequate. *Id.* § 82.007(b)(1)-(5). Plaintiff argues that the first exception, which provides as follows, applies to her and she has therefore rebutted the statutory presumption:

> the defendant, before or after pre-market approval or licensing of the product, withheld from or misrepresented to the United States Food and Drug Administration required information that was material and relevant to the performance of the product and was causally related to the claimant's injury.

Id. § 82.007(b)(1). Defendants argue that this exception is preempted by *Buckman* and therefore all of Plaintiff's claims that are rooted in a failure-to-warn theory—Count I (negligence), Count II (negligent failure-to-warn), Count V (fraud), Count VI (strict liability failure-to-warn), and Count XI (gross negligence)—should be dismissed as a matter of law.

ii. Buckman and Its Progeny

In *Buckman*, the Supreme Court considered whether the Federal Food, Drug, and Cosmetic Act ("FDCA") preempted state "fraud-on-the-FDA" claims. The plaintiffs alleged that a medical device manufacturer obtained FDA approval by making fraudulent misrepresentations to the agency; their sole claim was a fraud-on-the-FDA state law tort. *See Buckman*, 531 U.S. at 343. The Court explained that "[p]olicing fraud against federal agencies is hardly a field which the States have traditionally occupied," and thus the traditional presumption against federal preemption of a state law did not apply in the fraud-on-the-FDA context. *Id.* at 347 (internal quotations omitted). Thus, state law causes of action that are contingent upon the defendant making fraudulent representations to the FDA conflict with federal law and are, accordingly, preempted. *Id.* at 348.

The *Buckman* Court premised its analysis on "the relationship between a federal agency and the entity it regulates[, which] is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." *Id.* at 347. If state law fraud-on the FDA claims were permitted to proceed, the federal statutory scheme which empowers the FDA to investigate, punish and deter fraud would be skewed. *Id.* at 348. The flexibility and responsibility that the FDA has to take a measured response to fraud by seeking injunctive relief, pursuing civil penalties, criminally prosecuting, and seizing improperly approved product is a critical part of that statutory and regulatory framework. *Id.* at 349. Permitting state-law fraud-on-the-FDA claims would "inevitably conflict" with those FDA responsibilities. *Id.* at 350. Furthermore, if state law fraud-on-the FDA state law claims were viable, those who sought approval from the FDA for a product would be incentivized to submit a "deluge of information that the [FDA] neither wants nor needs, resulting in additional burdens on

the FDA's evaluation of an application[,]" *id.* at 351, all for fear that a state court may some day find their submission lacking even if the FDA had found it sufficient. Finally, the Court found that because fraud-on-the FDA claims exist "solely by virtue" of federal disclosure requirements and not through "traditional state tort law" there was a distinction to be made between the *Buckman* scenario and that found in *Medtronic v. Lohr, Inc.*, 518 U.S. 470, 495 (1996), in which the Court held that certain state-law causes of action that paralleled federal safety requirements could proceed without being preempted. 531 U.S. at 353-54. The Court reaffirmed this distinction in *Wyeth v. Levine*, 555 U.S. 555, 565 n.3 (2009), stating that *Buckman* "involved state-law fraud-on-the-agency claims, and the Court distinguished state regulation of health and safety as matters to which the presumption [against preemption] does apply."

Turning now to the effect of *Buckman* on Section 82.007 of the Texas Code: Although a handful and some cases have evaluated whether it (or another substantially similar Michigan statute) is preempted by the *Buckman* rationale, the Third Circuit has not. And, the decided cases, none of which are binding on this Court, are not in accord. Some have found preemption. *See Lofton*, 672 F.3d at 380; *Garcia v. Wyeth-Ayerst Labs*, 385 F.3d 961, 966 (6th Cir. 2004); *Gonzalez v. Bayer Pharms.*, 930 F. Supp.2d 808, 816 (S.D. Tex. 2013); *Murthy v. Abbott Labs.*, 847 F. Supp.2d 958, 976 (S.D. Tex. 2012); *Henderson v. Merck & Co.*, 2005 WL 2600220 (E.D. Pa. Oct. 11, 2005). Others have found no preemption. *See Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 97-98 (2d Cir. 2007); *Yocham v. Novartis Pharms. Corp.*, 736 F. Supp.2d 875, 887 (D.N.J. 2010); *Tigert v. Ranbaxy Pharms., Inc.*, 2012 WL 6595806 (D.N.J. Dec. 18, 2012).

The only case to have directly considered the question is *Lofton,* in which the sole issue presented to the Fifth Circuit was the effect of *Buckman* on Section 82.007(b)(1). *See* 672 F.3d at 375. Christopher Lofton died after ingesting an FDA-approved, over-the-counter pain

medication. His family sued the manufacturer for failure-to-warn under negligence and strict liability theories. *Id.* at 373-74. The defendants moved for summary judgment, asserting that the failure-to-warn claims which were subject to the fraud-on-the FDA proof requirement of Texas law were preempted by *Buckman*. *Id.* at 374-75. The district court granted summary judgment, and the plaintiffs appealed. *Id.* at 375.

The Fifth Circuit first analyzed whether the presumption against preemption should apply. *Id.* at 378. Because police powers traditionally belong to the states rather than the federal government, the Supreme Court has recognized "the historic primacy of state regulation on matters of health and safety" and applied a presumption against federal preemption in the pharmaceutical drug context. *See Medtronic*, 518 U.S. at 485; *see also Wyeth*, 555 U.S. at 565. But the Supreme Court in *Buckman* did not apply a presumption against preemption given the singular relationship between a federal agency and the entity it regulates. 341 U.S. at 347-48. Given the "uniquely federal" interest the FDA has in policing fraud against itself, no presumption was warranted in *Buckman*. *Id.* at 348. *Lofton*, in turn, relied on *Buckman*'s language to conclude that "the primacy of the state's police powers is not universal[.]" 672 F.3d at 378. Without assessing "the current scope or existence of the presumption against preemption," the Fifth Circuit took "refuge in the conclusion that because § 82.007(b)(1) requires a Texas plaintiff to prove fraud-on-the-FDA to recover for failure to warn this requirement invokes federal law supremacy according to *Buckman*." *Id.* at 379.

Next, the Fifth Circuit analyzed whether Section 82.007 is an "expression of traditional state common law." *Id.* "Traditional state tort law principles of the duty of care" are different from "any sort of fraud-on-the-agency theory[,]" with the former sometimes being allowed to proceed without being preempted, while the latter being impermissible if they "exist solely by

virtue of the FDCA disclosure requirements." *See Buckman*, 531 U.S. at 348-53. The Fifth Circuit concluded that Section 82.007(b)(1) was in the latter, impermissible category. *See* 672 F.3d at 379. Because Section 82.007(b)(1) requires a plaintiff to establish that a manufacturer withheld "required information that was material and relevant" from the FDA, this language both hinges on FDCA disclosure requirements and would require a court—*rather than the FDA itself*—to determine what is required, material, and relevant to the FDA. *Id.* In establishing a violation of FDA disclosure requirements, a plaintiff "necessarily re-treads the FDA's administrative ground." *Id.* at 380. Moreover, when the FDA itself has not found fraud, allowing courts "to interject varying views on what disclosures are sufficient" would interfere with the agency's processes—the very concern expressed in *Buckman*. *Id.* at 380; *see also Buckman*, 531 U.S. at 348-350. The Fifth Circuit therefore held that Section 82.007(b)(1) "is preempted unless the FDA itself has found fraud." *Id.* Subsequent Texas district court opinions followed *Lofton* in finding that Section 82.007(b)(1) was preempted. *See Gonzalez*, 930 F. Supp.2d at 816; *Murthy*, 847 F. Supp.2d at 976.

The Sixth Circuit, relying on similar reasoning, also found *Buckman* preempted the statutory fraud-on-the-FDA exception in an analogous Michigan statute.[7] *See Garcia*, 385 F.3d

[7] The relevant provision of Michigan law states:

> In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drugs administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller.

Mich. Comp. Laws § 600.2946(5). This immunity from liability does not apply if the defendant:

> [i]ntentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act and the drug would not have been approved, or the United States food and drug

at 966. The plaintiff was prescribed an anti-inflammatory medication that had been approved by the FDA, but the medication caused liver failure. *Id.* at 963. After she sued the drug manufacturer, it voluntarily withdrew the drug from the market; she submitted no evidence of the FDA finding fraud. *Id.* at 963 & 964 n.1. The Sixth Circuit recognized that the case presented a "somewhat different legal regime from the one invalidated in *Buckman*" given that Michigan created a "general immunity" for drug manufacturers with a specific exception for circumstances involving fraud on the FDA rather than a specific cause of action for fraud on the FDA but found this distinction "immaterial in light of *Buckman*." *Id.* at 965-66. The court concluded that preemption in this context depends on whether the FDA itself has found that fraud has been committed on the agency:

> Thus, in this setting, it makes abundant sense to allow a State that chooses to incorporate a federal standard into its law of torts to allow that standard to apply when the federal agency itself determines that fraud marred the regulatory-approval process. In the final analysis, the exemptions are invalid as applied in some settings (*e.g.* when a plaintiff asks a state court to find bribery or fraud on the FDA) but not in others (*e.g.* claims based on federal findings of bribery or fraud on the FDA).

Id. at 966; *see also Henderson v. Merck & Co.*, 2005 WL 2600220, at *9-*12 (E.D. Pa. Oct. 11, 2005) (following *Garcia* and finding Section 600.2946(5)(a) preempted).

By contrast, the Second Circuit reviewing the Michigan statute held that it was not preempted. *See Desiano*, 467 F.3d at 98. The court framed the cause of action not as a new tort based on fraud on the FDA, like in *Buckman*, but rather as an appropriate exercise of the state legislature regulating as to when victims could recover under preexisting state products liability law, as in *Medtronic*. *Id.* at 93. The court therefore held that the presumption against federal

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> administration would have withdrawn approval for the drug if the information were accurately submitted.

Mich. Comp. Laws § 600.2946(5)(a) (internal citations omitted).

preemption of state tort law applied. *Id.* at 94. It then found that the claims the plaintiffs advanced were "premised on traditional common law duties between a product manufacturer and Michigan consumers" and were not premised exclusively or even principally on a manufacturer's failure to comply with federal disclosure requirements. *Id.* at 94-95. Next the court noted that rather than fraud being a required element of a tort, the Michigan statute made it an affirmative defense under law, and preemption in that context "would go far beyond" other preemption cases. *Id.* at 96. Finally, the court found that as long as courts are allowed to consider evidence of agency fraud, pharmaceutical companies will always be incentivized to flood the FDA with information, and the holding in *Desiano* "would not significantly alter that incentive." *Id.* at 97.

iii. The Texas Statute is Preempted

The Fifth and Sixth Circuit opinions are the more persuasive of the competing precedents. Although this Court is not bound by the Fifth Circuit's rulings, it bears consideration that the Fifth Circuit, which is conversant with Texas law, found that the presumption against preemption did *not* apply in a Section 82.007(b)(1) case. *See Lofton*, 672 F.3d at 377-80. Moreover, the Fifth Circuit is the only federal appellate court to have interpreted the Texas exception at issue here, and it did so in a factually analogous circumstance involving common law tort claims after carefully considering the counter-arguments made in *Desiano*.

Section 82.007(b)(1) hinges on FDCA disclosure requirements and necessitates that a plaintiff establish the manufacturer withheld "required information that was material and relevant" from the FDA. The Texas exception therefore exists "solely by virtue of the FDCA disclosure requirements[,]" which *Buckman* used as a rationale for finding preemption. *See* 531 U.S. at 353. Thus, Section 82.007(b)(1) in effect asks a court to determine what is required, material, and relevant to the FDA, instead of allowing the FDA to make those determinations for

itself. *See Lofton*, 672 F.3d at 379-80 (finding *Desiano*'s emphasis on the distinction between a fraud-on-the-FDA tort and a fraud-on-the-FDA exception "unpersuasive" because the latter still conditioned recovery on "'establishing' what amounts to fraud on the agency").

Moreover, as the *Buckman* opinion described, the FDA is "amply empower[ed]" to investigate fraud, and having courts step into that role would "inevitably conflict" with the FDA's responsibilities. *See* 531 U.S. at 348-51. Plaintiff argues that "Defendants withheld from or misrepresented to the FDA pertinent clinical data as well as alarming studies linking Injectafer to a Severe Hypophosphatemia[,]" but does not allege that the FDA made any findings of fraud.[8] As the Sixth Circuit correctly held, the analysis would be different here if the FDA *had* found fraud and the plaintiff was suing in light of that finding to recover in tort. *See Garcia*, 385 F.3d at 966. But that is not the case. In the absence of such allegations of FDA findings of fraud, an inevitable conflict exists. *See Buckman*, 531 U.S. at 350; *see also Lofton*, 672 F.3d at 380 ("[W]here the FDA has not found fraud, the threat of imposing state liability on [a] drug manufacturer for defrauding the FDA intrudes on the competency of the FDA and its relationship with regulated entities."). Accordingly, for the reasons set forth above, the Section 82.007(b)(1) exception is here preempted.

Turning to the scope of the preemption, by statute it applies to any "products liability action alleging that an injury was caused by a failure to provide adequate warnings or information with regard to a pharmaceutical product." Tex. Civ. Prac. & Rem. Code

[8] In a motion to dismiss opinion in a related case, this Court stated: "Having failed to meet their burden, Defendants attempt to shift it to Plaintiff by suggesting that because 'Plaintiff pled no facts supporting a reasonable inference that the FDA lacked knowledge of the existing scientific data when it approved Injectafer,' her claims must be dismissed on impossibility preemption grounds. But preemption is an affirmative defense, and it is thus Defendants' burden, not Plaintiff's, to demonstrate that it applies." *Crockett*, 2020 WL 433367, at *8 (citing *Wyeth*, 555 U.S. at 573). That opinion was decided under Pennsylvania law, not Texas law as here. Moreover, the *Crockett* plaintiff stated that she was not advancing a "fraud on the FDA" theory, *see id.* at 6 n.14, while Plaintiff here is arguing the fraud-on-the-FDA exception to the Texas statute applies to her. The two cases therefore differ on these points.

§ 82.007(a). A "products liability action" for purposes of Section 82.007 is defined as:

> any action against a manufacturer or seller for recovery of damages arising out of personal injury, death, or property damage allegedly caused by a defective product whether the action is based in strict tort liability, strict products liability, negligence, misrepresentation, breach of express or implied warranty, or any other theory or combination of theories.

Tex. Civ. Prac. & Rem. Code § 82.001(2). From the text of the statute, it is clear that Count I (negligence), Count II (negligent failure-to-warn), Count VI (strict liability failure-to-warn), and Count XI (gross negligence) are preempted insofar as they are based on a failure-to-warn theory.

Defendants argue that Count V (fraud) is also preempted because the allegations are those of a negligent misrepresentation claim, merely relabeled as fraud. Defendants cite to one Texas district court case in support of their position. *See Gonzalez*, 930 F. Supp.2d at 820. But even though *Gonzalez* made a passing reference to "fraud-by-omission claims [being] subject to Section 82.007", *id.,* the court conducted no analysis to reach that conclusion (fraud had not been pled). The Fifth Circuit has found that the Texas products liability statute is "intentionally broad[,]" which suggests its reach should not be limited to the causes of action enumerated in Section 82.001(2). *See Eckhardt v. Qualitest Pharms., Inc.*, 751 F.3d 674, 678 (5th Cir. 2014) (noting the statute "is written to cover products liability claims, even in situations where the plaintiffs do not label their claims thusly."). Here, Plaintiff's fraud allegations focus on "false representations" and "Defendants' concealment and omissions of material facts[.]" These are failure-to-warn allegations cast under a different heading. Given that Section 82.001(2) applies to "any theory or combination of theories" alleging injury because of a failure-to-warn, the fraud claim here is preempted.

Because the drug manufacturer's rebuttable presumption in Section 82.007(a)(1) applies here, and because Plaintiff's only argument to rebut the presumption is preempted, Count I

(negligence), Count II (negligent failure-to-warn), Count V (fraud), Count VI (strict liability failure-to-warn), and Count XI (gross negligence) shall be dismissed with prejudice insofar as they are based on a failure-to-warn theory.[9]

B. Strict Liability Defective Design (Count VII)

Defendants argue Plaintiff's design defect claim fails under comment k to Section 402A of the Restatement (Second) of Torts,[10] which has been adopted by the Texas Supreme Court. *See Am. Tobacco Co., Inc. v. Grinnell*, 951 S.W.2d 420, 426 (Tex. 1997). The parties dispute whether comment k bars all strict liability defective design claims against prescription drug manufacturers. Defendants contend that it does. *See Hackett v. G.D. Searle & Co.* 246 F. Supp.2d 591, 595 (W.D. Tex. 2002) ("Defendants can only be held strictly liable if the drug was not properly prepared or marketed or accompanied by proper warnings."). Plaintiff argues that courts take a case-by-case approach to applying comment k. *See Lea v. Wyeth LLC*, 2011 WL 13192701, at *12 (E.D. Tex. Oct. 28, 2011) (collecting cases).

Even taking a case-by-case approach, Plaintiff's argument here fails. Plaintiff argues that

[9] Although leave to amend should be freely granted "when justice so requires . . . a court may deny leave to amend when such amendment would be futile." *Budhun v. Reading Hosp. and Med. Ctr.*, 765 F.3d 245, 259 (3d Cir. 2014) (internal quotations omitted).

[10] Comment k, titled "Unavoidably unsafe products," states: "There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk." Restatement (Second) of Torts § 402A cmt. k (1965) (emphasis in original).

in *Lea*, "the federal district court refused to bar plaintiff's strict liability design defect claims where the plaintiff also brought valid claims for inadequate warnings." But Plaintiff here does not have a valid claim for inadequate warnings. Significantly, *Lea* is a Texas district court opinion that was decided before the Fifth Circuit's *Lofton* opinion came down. *Lea* allowed the failure-to-warn claim to proceed, finding the Section 82.007(b)(1) fraud-on-the-FDA defense was not preempted, in contrast to the subsequent, binding *Lofton* decision and in contrast to the decision here. Comment k states that manufacturers are not strictly liable for design defects if "proper warning is given." *See* Restatement (Second) of Torts § 402A cmt. k. As discussed, *see supra* Section III.A, Texas has a rebuttable presumption that FDA-approved prescription drug labels are adequate, and Plaintiff here is unable to rebut that presumption. Because the warning here was adequate, given the unique circumstance presented by Section 82.007(b)(1), comment k applies, and there can be no strict liability defective design claim. Count VII shall be dismissed with prejudice.

C. Negligence (Count I) and Gross Negligence (Count XI)

Finally, Plaintiff asserts that even if claims based on her failure-to-warn theory are not viable, claims premised on a theory that Defendants failed to properly test Injectafer should survive.[11] Defendant argues that even assuming a failure-to-test claim can exist separately from a failure-to-warn claim, Plaintiff has not sufficiently pled a failure-to-test claim.

Under Texas law, "[a] manufacturer has a duty to test . . . [its] product. The extent of research . . . must be commensurate with the dangers involved." *Romero v. Wyeth Pharms., Inc.*,

[11] As pled, Counts I through IV contain a host of other theories against Defendants, such as negligence by "promoting, marketing, and selling Injectafer to physicians for the purposes of off-label use[,]" and "failing to establish and maintain an adequate post-marketing surveillance program[,]" among others. Because these theories have not been briefed and argued, the Court does not address them here.

2012 WL 12547449, at *4 (E.D. Tex. Aug. 31, 2012) (quoting *Borel v. Fibreboard Paper Prods. Corp.*, 493 F.2d 1076, 1090 (5th Cir. 1973) (alterations in original)). Thus, in Texas there is an independent cause of action based on negligent failure to test. *See, e.g.*, *Romero*, 2012 WL 12547449, at *4 (collecting cases); *Murthy*, 847 F. Supp.2d at 977 (recognizing a failure-to-test claim as distinct from a failure-to-warn claim, but dismissing it for failure to plead sufficient facts); *Am. Tobacco Co. v. Grinnell*, 951 S.W.2d 420, 437 (Tex. 1997) (recognizing plaintiff's negligent failure-to-test claim).

Here, the Complaint barely addresses testing. Plaintiff lists "testing" in a long list of other allegations ("development, testing, design, manufacture, inspection, marketing, pharmacovigilance, labeling, promotion, distribution and sale") and then alleges that Defendants failed "to perform reasonable pre- and post-market testing of the product to investigate Injectafer's propensity to cause Severe Hypophosphatemia." These "rote recitals of the elements of a cause of action, legal conclusions, and mere conclusory statements" are disregarded and are, accordingly, insufficient standing alone to state a claim for relief. *James*, 700 F.3d at 679. To the extent that a claim is premised on a theory of failure to properly test, it shall be dismissed with leave to amend the allegations regarding testing.

This includes Count I, which is Plaintiff's catchall negligence claim. Thus, none of Plaintiff's negligence claims survive this motion to dismiss. Without a valid negligence claim, Plaintiff's gross negligence claim fails. *See Sanders v. Herold*, 217 S.W.3d 11, 20 (Tex. App.–Houston [1st Dist.] 2006, no pet.) (holding that "one's conduct cannot be grossly negligent without being negligent"). Relatedly, without a gross negligence or fraud claim, Plaintiff has no basis for punitive damages under either Texas or Pennsylvania law. *See* Tex. Civ. Prac. & Rem. Code Ann. § 41.003 (exemplary damages only available for fraud, malice, or gross negligence);

Hutchison v. Luddy, 870 A.2d 766, 122, 125 (Pa. 2005) (punitive damages are for actions "so outrageous as to demonstrate willful, wanton or reckless conduct" and "a showing of ordinary negligence is not enough to warrant punitive damages").

An appropriate order follows.

March 23, 2020

BY THE COURT:

/s/Wendy Beetlestone, J.

WENDY BEETLESTONE, J.